

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Shone *et al.*

Appl. No.: 10/527,411

§ 371 Date: November 10, 2005

For: **Recombinant Toxin Fragments**

Confirmation No.: 7312

Art Unit: 1645

Examiner: Archie, Nina

Atty. Docket: 1581.0130005/TJS/JJY

**Reply to Restriction Requirement and Sequence Election**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated November 1, 2007, requesting an election of one invention to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the invention of **Group I**, represented by claims 1-30 and 40. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed. Applicants reserve the right to pursue the non-elected claims in one or more divisional applications.

This election is made **with** traverse.

At page 2 of the Office Action, the Examiner alleges that Groups I and II do not relate to a single general inventive concept because 1) the technical feature is anticipated by a fragment disclosed in the article by Willems *et al.*, in which a fragment of SEQ ID NO: 50 is "inherently capable of cleaving one or more vesicle or plasma membrane associated protein essential to exocytosis;" and 2) "the technical feature of Group II is a nucleic acid encoding a polypeptide." Applicants respectfully traverse.

In accordance with § 1893.03(d) of the Manual of Patent Examining Procedure ("MPEP"), "[w]hen making a lack of unity of invention requirement, the examiner must

(1) list the different groups of claims and (2) explain why each group lacks unity with each other (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group." *See* MPEP, Eighth Ed., Rev. Aug. 2007.

Claims 1-30, and 40 of Group I are directed to a single chain polypeptide comprising 1) a first domain of a clostridial neurotoxin light chain, its fragment, or variant, wherein the first domain is capable of cleaving a vesicle or plasma membrane associated protein essential to exocytosis; *and* 2) a second domain of a clostridial neurotoxin heavy chain, its fragment, or variant thereof, wherein the second domain is capable of translocating the polypeptide into a cell and/or increasing the solubility the polypeptide, *and* the second domain *lacks* a functional C-terminal part of a clostridial neurotoxin heavy chain, thereby rendering the polypeptide *incapable* of binding to cell surface receptors that are the natural cell surface receptors to which native clostridial neurotoxin binds. In contrast, the sequence provided in Willems *et al.* is a full length neurotoxin gene of a *C. botulinum* strain (Kyoto-F) with a functional C-terminal part of a clostridial neurotoxin heavy chain. *See* Willems *et al.*, Figure 2 ("Complete nucleotide sequence of the BoNT/A gene of *C. botulinum* Kyoto-F"); *see also*, STIC results provided by Examiner, at page 1 ("The C-terminus of the heavy chain (H) is responsible for the adherence of the toxin to the cell surface"). Therefore, Willems *et al.* sequence do not anticipate the technical feature of Group I.

Further, claims 31-37, 39, and 41 of Group II are directed to a nucleic acid encoding the single chain polypeptide of Group I. Accordingly, Group II also possesses the special technical features and should be examined together with Group I.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the Restriction Requirement. Applicants also retain the right to petition from the Restriction Requirement under 37 C.F.R. § 1.144.

***Sequence Election***

At pages 2-3 of the Office Action, the Examiner has also required an election of sequence. Applicants hereby provisionally elect amino acid sequence SEQ ID NO. 66 (claims 1-2, 5-7, and 12-18 are readable thereon).

These elections are made without prejudice to or disclaimer of the other claims or inventions disclosed.

These elections are made **with traverse**.

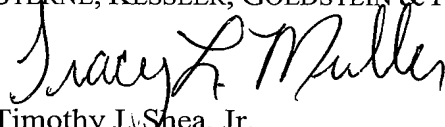
Applicants respectfully submit that special technical feature common to claims 1-37 and 39-41 is the single chain polypeptide comprising two domains with specific vesicle cleavage function and translocation and/or solubility function(s), as discussed above. Accordingly, the examination should encompass all of the recited sequences.

Thus, reconsideration and withdrawal of the Sequence Election, and consideration and allowance of all pending claims, are respectfully requested

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

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